CDRH - Premarket Notification (PMN or 510(k)) for 1997
October 1997 Listings
AUTO SUTURE BONE WAX

AUTO SUTURE BONE WAX

Decision Date: October 24, 1997 **Received:** May 7, 1997

Applicant	UNITED STATES SURGICAL, A DIVISION OF TYCO HEALTHC 150 GLOVER AVE. NORWALK CT 06856
Contact	MELISSA MAZZONI
510(k) Number	K971680 Summary in PDF
Decision	Substantially Equivalent (SE)
Statement/Summary	Summary/Purged 510(k)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Product Code	WAX,BONE (MTJ)
Type	TRADITIONAL
Third Party Review	No
Expedited Review	No

K971680

United States Surgical Corporation
510(k) Premarket Notification
Auto Suture* Bone Wax**

IX. 510(k) Summary of Safety and Effectiveness

OCT 24 1997

- SUBMITTER: United States Surgical Corporation
  150 Glover Avenue
  Norwalk, CT 06856

- CONTACT PERSON: Melissa Mazzoni

- DATE PREPARED: May 5, 1997

- CLASSIFICATION NAME: Unclassified

- COMMON NAME: Bone Wax

- PROPRIETARY NAME: Trademark name not yet determined

- PREDICATE DEVICES: Ethicon™ Bone Wax (preamendment)
  Lukens™ Bone Wax (K791495)

- DEVICE DESCRIPTION: Auto Suture* Bone Wax** is designed to control bleeding from bone surfaces by the creation of a mechanical barrier.

- INTENDED USE: Auto Suture* Bone Wax** is indicated for use in control of bleeding from bone surfaces.

- MATERIALS: All material components of Auto Suture* Bone Wax** have been evaluated for biocompatibility in accordance with ISO Standard #10993-1. The materials have been found to be safe for their intended use.

*Trademark of United States Surgical Corporation
**Trademark name not yet determined

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 1997

Ms. Melissa Mazzoni
Associate, Regulatory Affairs
United States Surgical Corporation
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K971680
Trade Name: Auto Suture* Bone Wax**
Regulatory Class: Unclassified
Product Code: MTJ
Dated: August 22, 1997
Received: August 26, 1997

Dear Ms. Mazzoni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications For Use:

510(k) Number (if known): K971680

Device Name: Auto Suture* Bone Wax**

Indications For Use:
Auto Suture* Bone Wax** is indicated for use in the control of bleeding from bone surfaces.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use:_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971680

*Trademark of United States Surgical Corporation
**Trademark name not yet determined